IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
ABINGDON

FEDERAL TRADE COMMISSION,

Plaintiff,

v.

RECKITT BENCKISER GROUP PLC,

Defendant.

Civil Action No. 1:19CV00028

STIPULATED ORDER FOR PERMANENT INJUNCTION AND EQUITABLE MONETARY RELIEF

Plaintiff, the Federal Trade Commission ("Commission" or "FTC"), filed its Complaint for Permanent Injunctive and Other Equitable Relief ("Complaint") in this matter pursuant to Section 13(b) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 53(b). The Commission and Reckitt Benckiser Group PLC, by their respective attorneys, have reached an agreement to resolve this case through settlement, and without trial or final adjudication of any issue of fact or law, and stipulate to entry of this Stipulated Order for Permanent Injunction and Other Equitable Monetary Relief ("Order") to resolve all matters in dispute in this action.

FINDINGS

1. The Court has jurisdiction over the subject matter and the parties to this action.

2. Venue for this matter is proper in this Court under 15 U.S.C. § 22 and 28 U.S.C. § 1391(b) and (c), and under Section 13(b) of the FTC Act, 15 U.S.C. §53(b).

3. The Complaint alleges that Defendant engaged in unfair methods of competition in violation of Section 5(a) of the FTC Act, 15 U.S.C. §§ 45(a), by engaging in anticompetitive activities designed to impede competition from generic equivalents of the brand-name drug Suboxone.

4. This Order does not constitute any evidence against Defendant, or an admission of liability or wrongdoing by Defendant in this case or in other litigation. This Order shall not be used in any way, as evidence or otherwise, in any other litigation or proceeding; provided that, nothing in this provision prevents the Commission or Defendant from using this Order in any proceeding regarding enforcement or modification of this Order or as otherwise required by law.

5. Entry of this Order is in the public interest.

STIPULATIONS

1. Defendant and Plaintiff, by and through their counsel, have agreed that entry of this Order fully and finally resolves all issues between them arising from the specific events giving rise to the allegations described in the Complaint and in the indictment in *United States v. Indivior Inc. et al.*, Case No. 1:19CR16 (W.D. Va. Apr. 9, 2019) and precludes further litigation between Plaintiff and Defendant on the resolved issues except for the purposes of enforcing or modifying this Order.

2. Defendant admits the facts necessary to establish personal and subject matter jurisdiction of this Court in this matter.

3. Defendant denies the charges in the Complaint and disputes that the Commission is entitled to obtain relief.

4. Defendant stipulates that it shall comply with the provisions of this Order pending its entry by the Court.

5. Defendant stipulates that it will bear its own costs in this matter and shall not make any claims against Plaintiff for attorney's fees or costs.

6. Defendant waives all rights to appeal or otherwise challenge or contest the validity of this Order.

7. Defendant waives any claim that it may have under the Equal Access to Justice Act, 28 U.S.C. § 2412, concerning the prosecution of this action through the date of this Order, and agrees to bear its own costs and attorney fees in this litigation.

DEFINITIONS

1. "Commission" means the United States Federal Trade Commission.

2. "RB Group" or "Defendant" means Reckitt Benckiser Group PLC and any joint venture, subsidiary, division, group, or affiliate Controlled currently or in the future by Reckitt Benckiser Group PLC, including but not limited to Reckitt Benckiser, LLC formerly d/b/a Reckitt Benckiser, Inc., Reckitt Benckiser Healthcare (UK) LTD., Reckitt Benckiser (North America) Inc., and Reckitt Benckiser USA General Partnership, as well as their successors and assigns, and the respective directors, officers, employees, agents,

representatives acting on behalf of each. For the avoidance of doubt, this definition does not include Reckitt Benckiser Pharmaceuticals, Inc., now known as Indivior, Inc.

3. "505(b)(2) Application" means an application filed with the United States Food and Drug Administration pursuant to Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(b)(2).

4. "ANDA" means Abbreviated New Drug Application filed with the United States Food and Drug Administration pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j).

5. "Authorized Generic" means a Drug Product that is manufactured pursuant to an NDA and Marketed in the United States under a name other than the proprietary name identified in the NDA.

6. "Citizen Petition" means a public request that the FDA issue, amend, or revoke a regulation or order or take or refrain from taking any other form of administrative action pursuant to 21 C.F.R. § 10.30.

7. "Commerce" has the same definition it has in 15 U.S.C. § 44.

8. "Control" or "Controlled" means the holding of more than 50% of the common voting stock or ordinary shares in, or the right to appoint more than 50% of the directors of, or any other arrangement resulting in the right to direct the management of, the said corporation, company, partnership, joint venture, or entity.

9. "Direct Cost" means the variable costs incurred to produce or sell an Original Drug Product or Follow-on Drug Product, including the costs of ingredients and manufacturing, as well as the costs of marketing that product. The term Direct Cost does

not include any allocation of overhead costs, administrative costs, research and development costs, or any other fixed costs.

10. "Drug Product" means a finished dosage form (e.g., tablet, capsule, solution, or patch) as defined in 21 C.F.R. § 314.3(b), approved under a single NDA, ANDA, or 505(b)(2) Application, and available by prescription, that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients. Notwithstanding the foregoing, the term Drug Product, as used in this Order, shall not include products that are predominantly purchased over-the-counter ("OTC") in the United States.

11. "Effective Price" means the net price paid by a payor for a Drug Product, taking into account all discounts, refunds, reimbursements, and rebates.

12. "FDA" means the U.S. Food and Drug Administration.

13. "Follow-on Drug Product" means a Drug Product a) for which Defendant has submitted an NDA, controls an approved NDA, or has the right to distribute in the United States; b) that contains an active ingredient that is (i) the same as an active ingredient in a previously approved Original Drug Product, or (ii) an isomer, salt form variant, or metabolite of an active ingredient in a previously approved Original Drug Product; and c) that treats the same condition or targets the same patient population as the previously approved Original Drug Product. Notwithstanding the foregoing, for purposes of this Order, the term Follow-on Drug Product shall not include an Authorized Generic version of the Original Drug Product.

14. "Market," "Marketed," or "Marketing" means the promotion, offering for sale, sale, or distribution of a Drug Product.

15. "NDA" means a New Drug Application filed with the United States Food and Drug Administration pursuant to Section 505(b) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(b), including all changes or supplements thereto that do not result in the submission of a new NDA.

16. "Original Drug Product" means a Drug Product that is Marketed in the United States and for which Defendant controls the NDA or has the right to distribute in the United States.

17. "Person" means any individual, partnership, joint venture, firm, corporation, association, trust, unincorporated organization, or other business, and any subsidiaries, divisions, groups, or affiliates thereof.

18. "Status Quo Period" means a period beginning the day Defendant begins Marketing a Follow-on Drug Product in the United States and ends on the earlier of (i) 6 months after a Third Party begins Marketing a Drug Product approved under an ANDA or 505(b)(2) Application for which the Original Drug Product is the reference listed drug, or (ii) 3 years after the day Defendant or a licensee of Defendant begins Marketing the Follow-on Drug Product in the United States.

19. "Third Party" means any Person other than Defendant.

ORDER

I. PROHIBITED ACTIVITY: CITIZEN PETITION PROCESS

IT IS ORDERED that if Defendant files a Citizen Petition, Defendant shall simultaneously disclose to both the FDA and the Commission:

A. All studies and data on which the Citizen Petition relies; and

B. All studies and data within the knowledge or possession of Defendant that address the validity or strength of one or more of the material contentions in the Citizen Petition.

Defendant shall provide such disclosure to the Commission by sending an electronic copy of the disclosure submission to the Compliance Division of the Bureau of Competition of the FTC at bccompliance@ftc.gov.

II. PROHIBITED ACTIVITY: PRODUCT SWITCHING CONDUCT

IT IS FURTHER ORDERED that:

A. Defendant shall provide a notification to the Plaintiff 30 calendar days after Defendant files an NDA for a Follow-on Drug Product in the United States. This notification shall be sent by electronic transmission to the Compliance Division of the Bureau of Competition of the FTC at bccompliance@ftc.gov and shall include, *inter alia*, the following information: (i) a reference to the Order, (ii) the NDA for the Follow-on Drug Product, and (iii) the associated Original Drug Product and NDA under which it is approved.

B. Defendant shall provide a second notification six months before the date specified for FDA approval of the Follow-on Drug Product under the Prescription Drug User Fee Act. This notification shall reference this Order and the previous notification submitted under Paragraph II.A. above for the Follow-on Drug Product. Defendants shall submit the following documents and information with the notification:

1. Documents sufficient to show the company's pricing plans for the Original Drug Product and Follow-on Drug Product;

2. Documents sufficient to show the forecasted sales for the Original Drug Product and Follow-on Drug Product;

3. Transcripts of any of the Defendant's investor calls during the prior twelve months that discuss the Follow-on Drug Product;

4. A statement of all claimed benefits of the Follow-on Drug Product compared to the Original Drug Product; and

5. A statement of whether Defendant intends to materially alter the terms on which it sells the Original Drug Product, and, if so, identification of these terms, and all reasons for materially altering them.

Defendant shall deliver this notification and the required documents to the Assistant Director of the Compliance Division of the Bureau of Competition of the FTC, either through electronic transmission to bccompliance@ftc.gov or hand-delivery to the FTC.

C. If, on the date when Defendant or its licensee begins Marketing a Follow-on Drug Product in the United States, a Third Party has submitted an ANDA or 505(b)(2) Application for which the Original Drug Product is the reference listed drug, then during the Status Quo Period, Defendant shall be prohibited from:

1. Destroying inventory or withdrawing from the market any strength or formulation of the associated Original Drug Product;

2. Failing to fill orders for the Original Drug Product on the same terms and conditions (except for those terms and conditions relating to Effective Price,

which are addressed below in Paragraph II.C.3) within the same time frame and with the same convenience as are orders for the Follow-on Drug Product;

3. Offering an Effective Price for the associated Original Drug Product to any Customer that is higher than the Effective Price Defendant offers to that Customer for the Follow-on Drug Product,

Provided, however, this prohibition does not apply (a) if the Effective Price of the Original Drug Product is not increased by more than the corresponding increase in the prescription drug price component of the Consumer Price Index at any time during the eighteen months prior to introduction of the Follow-on Drug Product or during the Status Quo Period; or (b) if the difference in Effective Price is attributable solely to a difference in the Direct Costs of the products; or

4. Deleting the National Drug Code for the associated Original Drug Product from the National Drug Data File;

Provided, however, that Defendant shall have no obligations under this Paragraph II.C with respect to an Original Drug Product: (a) for which the associated Follow-on Drug is no longer Marketed in the United States, or (b) that the FDA has determined should no longer be Marketed in the United States because of safety concerns.

III. EQUITABLE MONETARY RELIEF

IT IS FURTHER ORDERED that:

A. Judgment in the amount of fifty million dollars ($50,000,000) is entered in favor of Plaintiff against Defendant as equitable monetary relief.

B. Within 10 business days of entry of this Order, Defendant is ordered to pay Plaintiff fifty million dollars ($50,000,000) by electronic fund transfers in accordance with instructions previously provided by a representative of Plaintiff.

C. All money paid to Plaintiff pursuant to this Order may be deposited into a fund administered by Plaintiff or its designee to be used for equitable relief, including consumer redress and other equitable relief Plaintiff determines to be reasonably related to Defendant's alleged violative practices and injury, and any attendant expenses for the administration of such fund. Plaintiff shall deposit any money not used for such equitable relief in the U.S. Treasury. Any interest earned on amounts deposited into the fund will remain in the fund and become part of the fund.

D. Within 10 business days of entry of the Order, Defendant shall submit its Taxpayer Identification Number (Employer Identification Number) to Plaintiff.

E. Defendant shall have no rights to challenge any actions Plaintiff or its representatives may take pursuant to this Paragraph III. of the Order.

F. The payments provided for herein are provided for the purposes of settlement only, are remedial, and are neither a penalty nor a fine.

IV. NOTIFICATION REQUIREMENT

IT IS FURTHER ORDERED that Defendant shall notify the Commission within 30 calendar days of starting to Market, either directly or through a licensee, Drug Products in the United States by:

A. Receiving FDA approval to Market a Drug Product in the United States;

B. Acquiring Control of a Person that has FDA approval to Market a Drug Product in the United States; or

C. Acquiring or licensing a Drug Product that, at the time of such acquisition, has FDA approval to be Marketed in the United States.

Defendant shall provide such notification to the Commission by sending an electronic copy of the notification to the Compliance Division of the Bureau of Competition of the FTC at bccompliance@ftc.gov.

V. REPORTING REQUIREMENTS

IT IS FURTHER ORDERED that:

A. Defendant shall submit to Plaintiff a verified written report within 60 calendar days after the date this Order is entered, one year after the date this Order is entered, and annually for 9 years thereafter, setting forth in detail the manner and form in which Defendant has complied and is complying with this Order.

B. Defendant shall submit each report required under this Paragraph to the Secretary of the Commission and shall send an electronic copy of each report to the Compliance Division of the Bureau of Competition of the FTC at bccompliance@ftc.gov.

VI. CHANGE OF CORPORATE CONTROL

IT IS FURTHER ORDERED that

A. Defendant shall notify Plaintiff at least 30 calendar days prior to:

1. Any proposed dissolution of Reckitt Benckiser Group PLC;

2. Any proposed acquisition, merger, or consolidation of Reckitt Benckiser Group PLC; or

3. Any other change in Defendant, including, but not limited to, assignment and the creation, sale or dissolution of subsidiaries, if such change might affect the compliance obligations arising out of this Order.

B. No information or documents obtained by the means provided in this Paragraph VI. shall be divulged by the Commission to any person other than an authorized representative of the Commission, except in the course of a legal proceeding regarding enforcement of the Order, or as otherwise required by law.

VII. ACCESS TO INFORMATION

IT IS FURTHER ORDERED that:

A. For the purpose of determining or securing compliance with this Order or facilitating consumer redress pursuant to this order, and subject to any legally recognized privilege or any applicable privacy laws and regulations, Defendant shall, upon reasonable notice and in response to a written request by FTC staff:

1. Provide the FTC with documents and other electronically stored information in Defendant's possession, custody, or control, that are relevant to compliance or consumer redress under the Order; and

2. Permit Commission staff to interview officers, directors, or employees of Defendant, who may have counsel present, regarding matters that are relevant to compliance or consumer redress under the Order.

B. No information or documents obtained by the means provided in this Paragraph VII. shall be divulged by the Commission to any person other than an authorized representative of the Commission, except in the course of a legal proceeding regarding enforcement of the Order, or as otherwise required by law.

VIII. RETENTION OF JURISDICTION

IT IS FURTHER ORDERED that this Court shall retain jurisdiction of this matter for purposes of construction, modification, and enforcement of this Order.

IX. EXPIRATION OF THE ORDER

IT IS FURTHER ORDERED that this order shall expire 10 years after the date it is entered.

X. DISMISSAL AND COSTS

IT IS FURTHER ORDERED that this action shall be dismissed with prejudice and each party shall bear its own costs.

SO ORDERED this 12th day of July, 2019

United States District Judge

SO STIPULATED AND AGREED:

FOR PLAINTIFF FEDERAL TRADE COMMISSION:

Date: 7/8/19

Markus H. Meier
Assistant Director
Health Care Division
Bureau of Competition
Federal Trade Commission

FOR RECKITT BENCKISER GROUP PLC:

Date: 11 July 2019

Rupert M. Bondy
Senior Vice President, General Counsel and Company Secretary
Reckitt Benckiser Group plc

Date: July 11, 2019

Howard M. Shapiro
Wilmer Cutler Pickering Hale and Dorr LLP
Counsel to Reckitt Benckiser Group plc